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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/632,074	08/02/2000	Geoffrey Charles Nicholson	DAVI103.001AUS	9705

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EXAMINER

SAOUD, CHRISTINE J

ART UNIT PAPER NUMBER

1647

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/632,074

Applicant(s)

NICHOLSON, GEOFFREY
CHARLES

Examiner

Christine Saoud, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Election/Restrictions

- I. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-2, 4-5, and 17 (each in part), drawn to a method of modulating bone resorption in an animal comprising administering an effective amount of a leptin or a derivative, homologue, analogue, chemical equivalent, antagonist, or agonist wherein the elected species comprises an amino acid sequence having at least 60% similarity to the amino acid sequence set forth in *SEQ ID NO: 7*, classification dependent upon agent structure.
 - II. Claims 1, 3-5, and 17 (each in part), drawn to a method of modulating bone resorption in an animal comprising administering an effective amount of a leptin or a derivative, homologue, analogue, chemical equivalent, antagonist, or agonist wherein the elected species comprises an amino acid sequence having at least 60% similarity to the amino acid sequence set forth in *SEQ ID NO: 8*, classification dependent upon agent structure.
 - III. Claims 6-9 and 18, drawn to a method for inhibiting, reducing, or otherwise delaying onset of progression of bone resorption in an animal, classification dependent upon agent structure.
 - IV. Claim 10, drawn to a composition comprising a leptin having at least 60% similarity to the amino acid sequence set forth in *SEQ ID NO: 7*, classified in class 514, subclass 2.

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- V. Claims 13-14, 16, and 19 (each in part), drawn to a method for inhibiting osteoclastogenesis in an animal said method comprising administering an effective amount of a leptin or a derivative, homologue, analogue, chemical equivalent, antagonist, or agonist wherein the elected species comprises an amino acid sequence having at least 60% similarity to the amino acid sequence set forth in *SEQ ID NO: 7*, classification dependent upon agent structure.
- VI. Claims 13, 14-16, and 19 (each in part), drawn to a method for inhibiting osteoclastogenesis in an animal said method comprising administering an effective amount of a leptin or a derivative, homologue, analogue, chemical equivalent, antagonist, or agonist wherein the elected species comprises an amino acid sequence having at least 60% similarity to the amino acid sequence set forth in *SEQ ID NO: 8*, classification dependent upon agent structure.

2. The inventions are distinct, each from the other because of the following reasons:
3. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions I, II, III, V, and VI are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention I requires search and consideration of modulating bone resorption using a substance with at least 60% similarity to *SEQ ID NO: 7*, which is not required by any of the other Inventions. Invention II requires search and consideration of modulating bone resorption using a substance with at least

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60% similarity to *SEQ ID NO: 8*, which is not required by any of the other Inventions. Invention III requires search and consideration of inhibiting, reducing, or otherwise delaying onset of progression of bone resorption in an animal, which is not required by any of the other Inventions. Invention V requires search and consideration of method for inhibiting osteoclastogenesis using a substance with at least 60% similarity to *SEQ ID NO: 7*, which is not required by any of the other Inventions. Invention VI requires search and consideration of method for inhibiting osteoclastogenesis using a substance with at least 60% similarity to *SEQ ID NO: 8*, which is not required by any of the other Inventions.

4. Inventions IV and each of Inventions I, III, and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the composition of Invention IV can be used to isolate receptors (biochemical assay).

5. Inventions IV and each of II and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions IV and each of II and VI are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions II and VI do not recite the use or production of *SEQ ID NO: 7* of Invention IV.

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6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christine Saoud, Ph.D.** whose telephone number is **703-305-7519**. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D. can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN
March 21st, 2003


GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600